REMARKS

Claims 1-3, 6, 7, 13, and 14 are pending.

Claims 1, 3, 5, 13 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053). Claims 1, 3, 13 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by DuRoss (US 5,075,291). Claims 1-3, 6, 7, 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. Claims 1-3, 13 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over DuRoss in view of Okada et al.

Applicant would like to thank the Examiner for the interview on June 4, 2010 and herewith submits the Declaration of Dr. Chen Jianming clarifying the previous data submitted with the Declaration filed concurrently with the response to the office action of July 9, 2009. Applicant respectfully requests reconsideration in view of the remarks below.

Anticipation Rejection Over Okada et al.

The rejection of Claims 1, 3, 5, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053) is maintained for the reasons of record. The Examiner states that Applicant's arguments regarding the *en banc* decision of the Federal Circuit in *Abbott Labs v. Sandoz,* 566 F.3d 1282 (Fed. Circ. 2009) are unpersuasive because the Abbott Labs decision relates to findings regarding validity and infringement of a patent and not the examination of a patent application. The Examiner further states that given the differences in the formulations it is not possible to attribute the differences in property solely to the method by which the product was produced.

Applicant respectfully disagrees.

In general, to anticipate a claim, a reference must disclose, either explicitly or inherently, each and every element of the claim. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). With respect to product-by-process claims, in *Abbott*, the Federal Circuit, *en banc,* held that the limitations of a product-by-process claim do limit the claim in determining both infringement and validity. Applicant would like to point out that the *Abbott Labs* Court noted that the inventor will not be denied protection because the inventor chose to claim the product in terms of its process. 566 F.3d at 1294. Hence, to establish anticipation of a product-by-process claim,

the Examiner must show that the prior art discloses all of the claimed process limitations. *See Abbott Labs v. Sandoz*, 566 F.3d at 1293.

Claim 1 recites:

> 1. (Presently Amended) A drop pill comprising a pharmaceutical active ingredient and at least one pharmaceutically acceptable matrix adjuvants selected from a group consisting of D-ribose, fructose, glucose, xylose, trehalose, raffinose, maltose, gelose, sucrose ester, D-ribonic acid-γ-lactone; erythritol, sorbitol, xylitol, arabitol, isomaltitol, lactitol, malic acid, citric acid; said drop pill is prepared by **dripping** a solution, suspension, or emulsion of said pharmaceutical active ingredient with said at least one pharmaceutically acceptable matrix adjuvant **into a coolant. [emphasis added].**

Thus, claim 1 recites **dripping** a solution or suspension **into a coolant**. Okada et al. does not disclose these explicit limitations of claim 1. What Okada et al. discloses is a process wherein a mixture is charged into a mold, followed by air-drying. Thus, Okada et al. does not disclose every element of claim 1, either explicitly or inherently as required under *Abbott*. See *Abbott* 566 F.3d at 1293.

In addition, the product claimed in the present application is in fact different from the product of Okada et al. On January 11, 2009, Applicant submitted the Declaration of Dr. Chen Jianming showing that the product claimed in the present application is harder and has a significantly longer disintegration time than the product of Okada et al. (see paragraphs 9-11). Submitted herewith is a new Declaration of Dr. Chen Jianming which clarifies that identical formulations were used to produce the product identified as the "product of '078 application" and to produce the product identified as the "product of Okada et al." The only difference was the process used to prepare the products. Thus, in one instance, the process of Example 12 of the Okada et al. reference was used to form the "product of Okada et al." and in the other instance the process of Example 1 of the present application was used to produce the "product of '078 application." The differences in structure and properties of the resulting products were then evaluated. Applicant asserts that the structure and properties of the product of Okada et al. is different than the product of claim 1. Therefore, the

differences in the resulting product may be attributable solely to the method by which the product was produced.

Withdrawal of the anticipation rejection of independent claim 1 and dependent claims, 3, 13 and 14 over Okada et al. is respectfully requested.

II. Anticipation Rejection Over DuRoss

Rejection of Claims 1, 3, 13 and 14 under 35 U.S.0 102(b) as being anticipated by DuRoss (US 5,075,291) is maintained for the reasons of record. The Examiner further states that Applicant's arguments regarding the *en banc* decision of the Federal Circuit in *Abbott Labs v. Sandoz,* 566 F.3d 1282 (Fed. Circ. 2009) are unpersuasive because the Abbott Labs decision relates to findings regarding the validity and infringement of a patent and not examination of a patent application. The Examiner further states that based on the statements in the declaration, it is unclear what compositions were compared and thus the results presented in the declaration cannot be attributed to the different methods by which the products were produced.

Applicant respectfully disagrees.

Claim 1 recites **dripping** a solution or suspension **into a coolant**. DuRoss does not disclose these explicit limitations of claim 1. Thus, DuRoss does not disclose every element of claim 1, either explicitly or inherently as required under *Abbott*. See *Abbott* 566 F.3d at 1293.

In addition, the product claimed in the present application is in fact different from the product of DuRoss. On January 11, 2009, Applicant submitted the Declaration of Dr. Chen Jianming showing that the product claimed in the present application has different structure and properties (see paragraphs 14-17) from the DuRoss product. Applicant herewith submits a new Declaration of Dr. Chen Jianming which clarifies that identical formulations (using cimetidine as the active ingredient, sorbitol as the adjuvant and identical components) were used to evaluate the product formed using the process disclosed in Example 5 of DuRoss and the product formed using the process of Example 1 of the present application. Thus, the only difference is the process used to prepare the products, that is, the product identified as "the drop pill of the '078 application was prepared according to Example 1 of the present application and the product identified as the "product of DuRoss" was prepared according to Example 5 of the DuRoss reference. Therefore, the differences in the resulting product may be attributable solely to the method by which the product was produced.

Applicant asserts that the product of DuRoss is different than the drop pill of claim 1.

Withdrawal of the anticipation rejection of independent claim 1 and dependent claims 3, 13 and 14 over DuRoss is respectfully requested.

III. Obviousness Rejection Over Okada et al.

Rejection of Claims 1-3, 6, 7, 13 and 14 under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053) is maintained for the reasons of record. The Examiner further states that the declaration does not provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims. Therefore, this rejection is maintained.

Applicant respectfully disagrees.

To establish a *prima facie* case of obviousness, the Examiner must show that the prior art discloses, teaches or suggest each limitation of the claims at issue, MPEP §2143.03, or at least provides an "apparent reason" to modify the prior art in the direction of the claimed invention. The Examiner must further show that one skilled in the art would have a reasonable expectation of success to modify the prior art to arrive at the claimed invention.

As shown above, claim limitations "**dripping** ... **into a coolant**" are not found in Okada et al. reference. Moreover, one skilled in the art would have no apparent reason to modify the teachings of Okada et al. to arrive at the drop pill of the claimed invention. The objective of Okada et al. is to provide solid preparation which disintegrates and dissolves rapidly. See Okada et al., column 1, lines 66-67 to column 2, line 1. To achieve the rapidly dissolving product the Okada et al. process requires, *inter alia*, removal of moisture or solvent from the mixture, and evaporation during formation of the solid. This results in many micro-pores being produced during the preparation. As a result, the preparation disclosed by Okada et al. produces a product that is loose in structure with many micro-pores, capable of rapid dissolution. In contrast, in the process claimed in the present application, no evaporation or sublimation occurs during the formation of a drop pill, and thus, no micro-pores are produced. Thus, Okada et al. does not disclose, teach or suggest every limitation of the rejected claims. Hence, the Examiner has not established a *prima facie* case of obviousness.

Furthermore, Applicant surprisingly found advantages over the rapidly dissolving

preparation disclosed by Okada et al. For example, the claimed drop pills of the present application are denser and have a slower disintegration time, resulting in a product that is more resistant to pressure, is easier package, transport and store.

Applicant herewith submits a new Declaration of Dr. Chen Jianming which clarifies that identical formulations were used to evaluate the product formed using the process disclosed in Example 12 of Okada et al. with the product formed using the process disclosed in Example 1 of the present application. Thus, the Declarations provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims.

Withdrawal of the obviousness rejection of claims 1-3, 6, 7, 13 and 14 over Okada et al. is respectfully requested.

Obviousness Rejection Over DuRoss in view of Okada et al.

Rejection of Claims 1-3, 6, 7, 13 and 14 under 35 U.S.C. 103(a) as being unpatentable DuRoss (US 5,075,291) in view of Okada et al. (US 6,455,053) is maintained for the reasons of record. The Examiner further states that the declaration does not provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims. Therefore, this rejection is maintained.

As indicated above, the claim limitations "**dripping** … **into a coolant**" are not found in either DuRoss or Okada et al. reference. Thus, neither DuRoss nor Okada et al., alone or in combination teach, disclose or suggest every limitation of the rejected claims. Hence, the Examiner has not established a *prima facie* case of obviousness.

Furthermore, one skilled in the art would have no "apparent reason" to modify the teachings of DuRoss in the direction of the claimed invention. DuRoss discloses a process for the controlled crystallization of a melt, wherein the melt (consisting of the pharmaceutical active ingredient and a sugar alcohol) is placed on a tray to dry and slowly cooling until crystallized. The product of DuRoss has to be further modified to provide a powder that can be make into tablets. Okada et al. discloses a method of producing a rapidly dissolving product wherein a suspension of

the active and saccharide are charged into a mold and air-dried followed by additional slow drying. Modification of the process of DuRoss with the teachings of Okada et al would not result in the formation of the drop pill as claimed in the present application. One skilled in the art would simply have no reasonable expectation of obtaining the drop pill of the rejected claims by modifying the process of DuRoss with the extract of Okada et al.

As indicated above, Applicant herewith submits a new Declaration of Dr. Chen Jianming which clarifies that identical formulations were used to evaluate the product formed using the process of Example 5 of DuRoss with the product formed using the process of Example 1 of the present application. Likewise, identical formulations were used to evaluate the product formed using the process of Example 12 of Okada et al. with the product formed using the process of Example 1 of the present application. Thus, the Declarations provide evidence of comparisons between the most relevant examples in the cited prior art and evidence commensurate in scope with the full breadth of the instant claims.

Withdrawal of the obviousness rejection of claims 1-3, 6, 7, 13 and 14 over DuRoss in view of Okada et al. is respectfully requested.

Status of Claims

Applicant does not wish to withdraw claim 6 from further consideration.

The Applicant therefore respectfully requests reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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